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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/540,311

12/12/2005

Meena Augustus

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4638

27162 7590 06/19/2007
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EXAMINER

BAUGHMAN, MOLLY E

ART UNIT

PAPER NUMBER

1637

MAIL DATE

DELIVERY MODE

06/19/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/540,311

Applicant(s)

AUGUSTUS ET AL.

Examiner

Molly E. Baughman

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-59 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-59 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-9, 21-27, and 46, drawn to a method for identifying a TRIP13 gene modulating agent comprising determining a change in expression of said gene after cell is contacted with a test compound.

Group II, claim(s) 10-15, drawn to a method for identifying an anti-neoplastic agent comprising detecting a change in activity of a cancerous cell contacted with said agent.

Group III, claim(s) 16-18, and 28-30, drawn to a method for detecting the cancerous status of a cell or a method of detecting cancer or a predisposition toward developing cancer via a sample from a patient.

Group IV, claim(s) 19-20, drawn to a method of detecting a cancer-linked gene.

Group V, claim(s) 31-39, and 57-59, drawn to a method for treating cancer comprising contacting a cancerous cell with an agent identified as having gene modulating activity and in an effective amount to cause a reduction in cancerous activity of said cell.

Group VI, claim(s) 40-45, and 47-50, drawn to a method for monitoring the progress of cancer therapy or a treatment for cancer in a patient afflicted therewith.

Group VII, claim(s) 51-53, drawn to a method for determining the survival prognosis of a patient afflicted with cancer.

Group VIII, claim(s) 54-56, drawn to a method for determining the likelihood of survival of a patient afflicted with cancer.

2. The inventions listed as Groups I-VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the special technical

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feature, the detection of the TRIP13 gene in cancerous cells and compounds which modulate its expression, does not provide contribution over the prior art (see Roninson et al., US 2004/0058320 A1, Table 1 - pg.14).

Restriction Subgroups

This application contains claims directed to the following patentably distinct Restriction Subgroups of the claimed invention. Under PCT Rule 13.3, the determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or *as alternatives within a single claim*.

Each of the nucleotide sequences comprise a patentably distinct subgroup.

According to the Official Gazette (OG) of the Patent Office (Mar.27, 2007) (shortened):

"The office has reconsidered the policy set forth in the 1996 Notice [i.e. up to ten, independent and distinct molecules described by the nucleotide sequence] in view of the changes in the complexity of applications filed, the types of inventions claimed and the state of the prior art in this technology since that time. Because of these changes, the search and examination of up to ten molecules described by their nucleotide sequence often consumes a disproportionate amount of Office resources over that expended in 1996. Consequently, with this Notice the Office rescinds the partial waiver of 37 CFR 1.141 *et seq.* for restriction practice in national applications filed under 35 U.S.C. 111(a), and 37 CFR 1.475 *et seq.* for unity of invention determinations in both PCT international applications and the resulting national stage applications under 35 U.S.C. 371. This Notice is effective immediately and is applicable to all pending applications." As such, "claims to polynucleotide molecules will be considered for independence, relatedness, distinction, and burden as for claims to any other type of molecule."

As such, applicant is required under PCT Rule 13.3 to elect a single disclosed Subgroup consisting of no more than one Sequence ID from each SEQ ID Group (Group 1 - polynucleotides: SEQ ID NO: 1-6, Group 2 - polypeptides: SEQ ID NO: 7-12) from the elected invention above for prosecution on the merits to which the claims shall be restricted. For example, if the applicant were to elect Group 1, (s)he could also

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further elect SEQ ID NO:3 and SEQ ID NO: 9; i.e. a total of two Sequence IDs, one from each group.

Applicant is advised that a reply to this requirement must include an identification of the restriction subgroup that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election. Should applicant traverse on the ground that the Restriction Subgroups are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the Restriction Subgroups to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

3. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Molly E. Baughman whose telephone number is 571-272-4434. The examiner can normally be reached on Monday-Friday 8-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Molly E Baughman
Examiner
Art Unit 1637

MEB 6/12/07

Kenneth R. Horlick
KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER

6/13/07